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## 510(k) Summary of Safety and Effectiveness

MAR - 4 1996

The following information is submitted in accordance with 21 CFR 807.92:

**Submitted by:**

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**Proprietary Name:** Storz Ophthalmic Bipolar Cautery Instruments and Bipolar Cords

**Common/Usual Name:** Ophthalmic Bipolar Cautery Devices

**Classification Name:** Apparatus, Cautery, Radiofrequency, AC powered; 86(HQR)

**Device Description:** Storz D8200 series Ophthalmic Bipolar Cautery devices are accessories to Storz DAISY®, Protégé®, and PREMIERE® Ophthalmic Microsurgical Systems. The D8200 is a reusable bipolar forceps, D8201 is a reusable bipolar eraser, and the D8203 is a reusable bipolar intraocular eraser. The D8202 bipolar cord is used to connect the three cautery instruments to the Storz DAISY® Microsurgical System; the D8204 bipolar cord is used to connect the three cautery instruments to the Storz Protégé® and PREMIERE® Microsurgical Systems. All three instruments and both cords have Lemo™ locking connectors. The D8200 forceps are composed of surgical grade stainless steel; the D8201 and D8203 erasers are composed of surgical grade stainless steel and spring steel, and liquid crystal polymer insulation. These materials raise no questions of biocompatibility.

**Intended Use:** The Storz Ophthalmic Bipolar Cautery devices are used to control bleeding during ophthalmic surgical procedures using radiofrequency electric current. The D8200 Bipolar Forceps are used during ophthalmic procedures, coagulating extraocular tissue by pinching it between the forcep tips. The D8201 Bipolar Eraser is also used during surgery for cauterization of extraocular vessels, while the D8203 Bipolar Intraocular Eraser is used in posterior ophthalmic surgical procedures to cauterize vessels internal to the eye.

**Predicate Devices:** The Kirwan Ophthalmic Bipolar Forceps, Bipolar Pencils, and Bipolar Cord (Kirwan Surgical Products, Inc.); and Mentor WET-FIELD Bipolar Forceps and Bipolar Hemostatic Erasers (Mentor O & O, Inc.).

**Predicate Comparison:** Tables comparing the Storz Ophthalmic Bipolar Cautery devices to predicate devices, demonstrating substantial equivalence, are attached.

# D8200 Substantial Equivalence Comparison

Manufacturer	Storz Instrument Company	Kirwan Surgical Products, Inc.	Mentor O & O, Inc.
Device	Storz Ophthalmic Bipolar Forceps	Kirwan Ophthalmic Bipolar Forceps	Mentor WET-FIELD Ophthalmic Forceps
Model(s)	Model D8200	Several models	Models 22-1204, 22-1206, 22-1207, and 22-1209
Intended Use	Extraocular cauterization	Extraocular cauterization	Extraocular cauterization
Patient-Contact Material Composition	Stainless steel	Stainless steel	Unknown
System for which device is designed	Storz DAISY®, Protec® <sup>®</sup> , and PREMIERE® Ophthalmic Microsurgical Systems	Any compatible system	Mentor WET-FIELD II Coagulator
Connector type	Lemo™ locking connector	Two-pin plug	Two-pin plug
Reusable/Single Use?	Reusable	Reusable and Single Use models	<del>Single Use</del> Reusable (See Amendment)
Provided Sterile?	No	Reusable - No Single Use - Yes	Unknown

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D8203 Substantial Equivalence Comparison

Manufacturer	Storz Instrument Company	Kirwan Surgical Products, Inc.	Mentor O & O, Inc.
Device	Storz Ophthalmic Bipolar Intraocular Diathermy	Kirwan Ophthalmic Bipolar Pencils	Mentor WET-FIELD II® Ophthalmic Hemostatic Erasers
Model(s)	Model D8203	Models 14-5004, 14-5006, 14-7006, and 14-7008	Models 22-1260, 22-1265
Intended Use	Intraocular cauterization	Intraocular cauterization	Intraocular cauterization
Tip Configuration	Steep taper, sharp tip, 20 gauge	14-5004/14-7006 - gradual taper, sharp tip, 20 gauge; 14-5006/14-7008 - steep taper, sharp tip, 23 gauge	22-1260 - gradual taper, sharp tip, 20 gauge; 22-1265 - steep taper, sharp tip, 23 gauge
Patient-Contact Material Composition	Stainless steel outer electrode, Spring steel inner electrode, Liquid crystal polymer insulation	Stainless steel; other materials unknown	Unknown
System for which device is designed	Storz DAISY®, Protege®, and PREMIERE® Ophthalmic Microsurgical Systems	Any compatible system	Mentor WET-FIELD II® Coagulator
Connector Type	Lemo™ locking connector	Two-pin plug	Two-pin plug
Reusable/Single Use?	Reusable	14-5004/14-5006 - Single Use, 14-7006/14-7008 - Reusable	Single Use
Provided Sterile?	No	Single Use - Yes Reusable - No	Yes

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# D8202/D8204 Substantial Equivalence Comparison

Manufacturer	Storz Instrument Company	Kirwan Surgical Products, Inc.
Device	D8202 and D8204 Storz Ophthalmic Bipolar Cords	Kirwan Model 10-6010 Bipolar Cord
Intended Use	<b>D8202</b> - To connect D8200, D8201, D8203 cautery instruments to Storz DAISY Microsurgical System <b>D8204</b> - To connect D8200, D8201, D8203 to Storz Protege and PREMIERE Microsurgical Systems	Connects cautery instruments to compatible coagulator system
Connector Type	Lemo™ Locking connectors on both ends of cords	Lemo™ locking connector to coagulator system; Two-pin plug to instrument
Reusable/Single Use?	Reusable	Reusable
Provided Sterile?	No	No
Cord insulation material/size	Thermoplastic rubber/ Six feet long	Silicone/ twelve feet long

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